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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,143	07/25/2003	Mark S. Spector	N.C. 84,766	3910

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EXAMINER

HANLEY, SUSAN MARIE

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/627,143

Applicant(s)

SPECTOR ET AL.

Examiner

Susan Hanley

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 1-26, 28 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27, 30, 31 and 33 is/are rejected.
- 7) ☒ Claim(s) 32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1651

DETAILED ACTION

Election/Restrictions

Applicant's election of Group II, claims 27-33, the hydrogel specie of claim 18 and a protein as the analyte in the reply filed on 4/20/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-26, 28, and 29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/20/06.

Claims 27 and 30-33 are presented for examination.

Specification

The abstract of the disclosure is objected to because it is too long. The abstract should have a maximum of 250 words. Correction is required. See MPEP § 608.01(b).

Claim Suggestion

In claim 31, it suggested that the phrase "based on biomolecule" be amended to read "based on a biomolecule".

Claim Objections

Claims 31 and 32 are objected to because of the following informalities: Claims 31 is objected to because "fluorophore" is misspelled. Claims 32 is objected to because "Staphylococcal" is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1651

Claims 27 and 30-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 27 and 33 are rejected because they depend from one or more withdrawn claims.

Claim 27 is rejected, insofar as the specie election reads on "a 2-acrylamidohydroxyacetic acid" as recited in claim 18 because use of the article "a" implies that derivatives of 2-acrylamidohydroxyacetic are also claimed. The specification does not describe the nature of structure of these derivatives. Hence, the phrase is indefinite because its metes and bounds are undefined.

Claim 27 is rejected insofar as the elected hydrogel specie of claim 18 depends from claim 1 for the definition of the structure of the elected hydrogel specie. The structure in Figure 1 contains the variables R1-R10 that are not defined in claim 1 or claim 18. Therefore, the metes and bounds of the variables are undefined and the claim is vague and indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 27, 30, 31 and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Boschetti et al. (US 2003/0218130; referred to as "Boschetti").

Boschetti discloses a method for assaying analytes with a device comprising a support having a polysaccharide-based hydrogel attached to an anchor reagent on a substrate surface. The attached

Art Unit: 1651

hydrogel is derivatized with a binding moiety to selectively bind one or more analytes from a sample (abstract).

Boschetti discloses several reaction pathways to achieve the immobilized, derivatized hydrogels. The anchor reagent is bound to the substrate surface. The anchor reagent can be methacryloyloxypropyltrimethoxy silane or glycidyl methacrylate (p. 15-16, bridging paragraph and Fig. 5), both of which meet the limitation of an acrylate functionalized support, as in instant claim 27A. In one embodiment, a modified polysaccharide having a first polymerizable moiety and a polymerization initiator are contacted with the substrate surface comprising the bound anchor reagent having a second polymerizable moiety (the acrylate). Co-polymerization takes place to yield a hydrogel comprising a derivatized polysaccharide that is grafted to the surface of a device via links resulting from the polymerization reaction (section 0104), as in instant claim 27B. Boschetti discloses that the modified polysaccharide used in the polymerization reaction can be cross-linked by typical cross-linkers such as bisacrylamide or those disclosed in section 0019 to couple the polymerizable moieties on the polysaccharides (sections 0105). Bisacrylamide has two double bonds and meets the structural limitation for the cross-linkers recited in instant claim 1. Binding functionalities can be provided before polymerization of the derivatized, cross-linked polysaccharide to the device surface having the second polymerizable moiety (section 0107).

The disclosure of a derivatized polysaccharide is a dextran that is derivatized with polymerizable group including allyl, acryloyl, methacryloyl and vinyl (section 0074-0075), meets the structural requirements of the sugar compound recited in instant claim 1. The disclosed hydrogel can comprise binding functionalities such as sulfonate, phosphate, amino, thiol or carboxyl, for example. A carboxyl binding group is achieved by incorporating 2-acrylamidoglycolic acid or derivatives thereof (section 0082). This disclosure meets the elected specie of instant claim 18, a 2-acrylamidohydroxyacetic acid, because 2-acrylamidoglycolic acid is a synonym for 2-acrylamidohydroxyacetic. The disclosure of 2-

Art Unit: 1651

acrylamidoglycolic acid meets the limitations regarding the third compound listed in instant claim 1 because it comprises a polymerizable double bond ("acryl") and a carboxyl group.

The immobilized hydrogel comprising dextran having a double bond, a cross-linker with two double bonds and a binding functionality this is a carboxyl group via the elected third compound recited in instant claim 18, is then reacted with a biomolecule such as a polypeptide, protein, carbohydrate, lipid or nucleic acid which can be used to bind receptors, antibodies, small organic compounds, etc. (section 0123 and claim 67 of the referenced patent). This disclosure meets part D. of instant claim 27. The disclosure of a protein as the attached biomolecule satisfies instant claim 30. The biomolecule can be labeled with a fluorophore, as in instant claim 31 (assuming that "fluorophrone" is "fluorophore"). An example is FITC-labeled Concanavalin A (section 0181). Boschetti teaches that the assays using the disclosed immobilized hydrogels can be detected by fluorescence, UV, visible, immuno methods, for example (sections 0137-0140), as in instant claim 33 (assuming that instant claim 33 was intended to depend from instant claim 27). Boschetti discloses that the functionalized hydrogel was used to assay for glucosides and mannosides (section 0192-0193), thus meeting the assay step in instant claim 27D.

No claim is allowed.

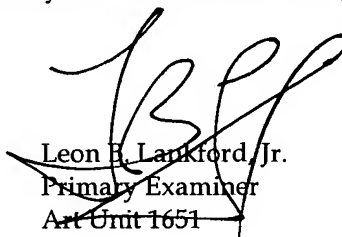
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1651

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Susan Hanley
Patent Examiner
1651



Leon B. Lankford, Jr.
Primary Examiner
Art Unit 1651